

May 10, 2019

Hon. William L. Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 6101A
Washington, DC 20460

Re: EPA Risk Assessment for Ethylene Oxide in Willowbrook, Illinois: Ambient Air Monitoring Data

Dear Mr. Wehrum:

We write regarding EPA's stated intention to complete a risk assessment regarding ethylene oxide levels in the Willowbrook, Illinois area near Sterigenics' Willowbrook facility. Specifically, our concerns relate to the possibility that ambient monitoring data might be used in some manner in the analysis. As discussed below, we have significant concerns about the accuracy and significance of EPA's ambient air monitoring because of additional information the company has been able to compile. This information includes identification of ethylene oxide sources that, to our knowledge, EPA to date has not considered in its review of the Willowbrook area, and data quality issues that call into question the validity and accuracy of ambient air monitoring results.

As you know, ambient monitoring data can identify the level of a particular chemical or compound in the atmosphere at a specific location and point in time. Ambient monitoring does not, however, identify the source of the detected material. We are unaware of any effort by EPA, in collecting ambient monitoring data in Willowbrook, to secure and maintain the integrity of the monitoring locations while EPA's canisters were deployed in Willowbrook for the November to March monitoring program. In fact, we have evidence of unidentified individuals handling canisters during the test period. Similarly, we are not aware of any efforts by EPA or any of the other federal, state, and local agencies that have studied or opined on conditions in Willowbrook to identify other potential sources of ethylene oxide emissions. Sterigenics recognizes that its facility has some level of emissions, and when allowed to operate, the facility kept its emissions far below permitted levels. Nevertheless, we believe that at least some of the ambient air concentrations of ethylene oxide that EPA measured are likely from other sources.

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First, throughout the entire time period during which EPA conducted its monitoring, substantial construction activities took place immediately adjacent to EPA’s monitoring canisters at the “Village Hall” location. We obtained the specifications of the materials actually used during this significant building-wide renovation project, as some building materials contain ingredients that can reasonably be expected to contain or produce ethylene oxide during use. Indeed, through testing some of the materials that were actually used at the adjacent construction site during the EPA’s monitoring program, we confirmed that some materials give off significant ethylene oxide to the surrounding air. While our data are not final, as they are currently undergoing additional quality assurance testing, our efforts are ongoing. Notably, these construction activities ceased in mid-February 2019, about the same time the Willowbrook facility ceased operating.

We also know that mobile sources can have a significant impact on ambient ethylene oxide levels. Sterigenics sampled the exhaust from diesel and gasoline-powered vehicle engines, both before and after catalytic converters, for ethylene oxide. We then used information from publicly-available sources to estimate ethylene oxide emissions to the atmosphere for each of the counties in the Chicago metropolitan area. A white paper describing this analysis in greater detail is attached to this letter. As the white paper indicates, we estimated approximately 52,000 pounds of ethylene oxide emitted from vehicles in the Chicago area each year, with 6,800 of those pounds emitted in DuPage County alone:

Estimated Annual Ethylene Oxide Emissions (lbs. /yr.) in Chicago Area Counties from Mobile Sources			
<i>County</i>	<i>Diesel- Powered Fleet</i>	<i>Gasoline- Powered Fleet</i>	<i>Total</i>
Cook	26,499	114	26,613
DuPage	6,772	28	6,800
Will	5,843	19	5,862
Lake	5,032	19	5,051
Kane	4,065	13	4,078
McHenry	2,416	8	2,424
Kendall	931	3	934
<i>Total</i>	<i>51,558</i>	<i>204</i>	<i>51,762</i>

Given the high level of traffic in the Willowbrook area and very near to the EPA’s ambient sample locations in the commercial area, it is likely that vehicle emissions had a material impact on EPA’s ambient air monitoring results.

Everyday sources – such as home heating furnaces, boilers, and grills – also contribute to ethylene oxide levels because common fossil-fuel sources result in ethylene oxide emissions. We have sampled the air surrounding several everyday sources of ethylene oxide,

including propane grills, wood-burning stoves, natural gas furnaces, and gasoline-powered lawn mower engines. This investigation was performed consistent with EPA methods by placing the everyday sources in an enclosure and operating them, and then sampling and analyzing air from the enclosures for ethylene oxide. Average ethylene oxide concentrations detected in the enclosure from these everyday sources were:

<i>Source</i>	<i>Average Concentration ($\mu\text{g}/\text{m}^3$)</i>
Propane grills	86.7
Wood-burning stoves	84.7
Gas-powered lawn mower engines	75.3
Natural gas furnaces	0.577

A suburban community, such as Willowbrook, undoubtedly has large numbers of these everyday sources in use. The businesses and government buildings near Sterigenics' Willowbrook facility must also operate boilers and other fossil fuel-powered sources that emit similar ethylene oxide emissions. In fact, the EPA office directly behind our facility operates a diesel backup generator about 40 feet from one of the monitoring locations. The ethylene oxide emission rates from these everyday sources are large enough that they should be considered when assessing any ambient air monitoring results from the Willowbrook area.

Finally, there is a general background level of ethylene oxide. Sterigenics has demonstrated that background concentrations of ethylene oxide exist throughout the Chicago area, including in areas that are not near any known industrial ethylene oxide sources. Sterigenics commissioned Ramboll, a respected science and engineering consulting firm, to study the ambient conditions in the greater Chicagoland area. Ramboll sampled ambient air in October and November 2018 from a variety of Chicago area locations, from Golden Gate Park south of Chicago to Highland Park in the north and from Lake Michigan west out to Naperville. An independent laboratory analyzed these 76 samples and measured ethylene oxide concentrations that ranged from $0.09 \mu\text{g}/\text{m}^3$ to $1.10 \mu\text{g}/\text{m}^3$. The mean concentration of the October 2018 samples was $0.28 \mu\text{g}/\text{m}^3$, and the mean concentration of the November 2018 samples was $0.21 \mu\text{g}/\text{m}^3$. Additional information about these data is available at www.sterigenicswillowbrook.com.

If we understand correctly, EPA intends to use monitoring data in combination with modeling results in its risk assessment. However, using the ambient data and assuming that the measured values are primarily due to Sterigenics' operations introduces a very significant risk of error, particularly when both the measured values, Sterigenics' emissions, and the risk-based concentrations being targeted are all very low numbers.

In light of these and other facts, we ask that EPA pay particular attention to the following points as it addresses ambient air monitoring data in its risk assessment:

- The ethylene oxide background concentrations represent a practical minimum level that will always exist in the Willowbrook community, regardless of what permit limits or other regulations are applied to the Sterigenics facility and no matter whether the facility is permitted to re-open.
- The pervasive presence of background ethylene oxide levels calls into question the methodology used in the December 2016 IRIS assessment of ethylene oxide, since the inhalation unit risk level was set without regard to ubiquitous background concentrations of ethylene oxide.
- Ethylene oxide's presence in all communities, and from sources that are familiar to U.S. households, is a vital fact in characterizing and communicating any potential risk to residents. It is important that the public know that ethylene oxide is ubiquitous and is emitted from many common sources and items that the public uses in everyday activities.

If EPA's risk assessment is to be fair and scientifically reliable, it also must take a hard look at data quality issues and incorporate them in its analysis. The information above stresses several data quality issues that call the validity of EPA's air monitoring data for risk assessment purposes into question:

- During the sampling period, the Village's "Board and Community Center" at 825 Midway Drive underwent significant roofing and façade renovations. As described above, construction products – including some of the products actually used in this renovation work – contain and give off ethylene oxide. The construction work on Midway Drive – located within feet of and immediately adjacent to a sampling location used by EPA and the Village for air monitoring (described as "Village Hall" in EPA's monitoring results) – began in approximately November 2018 and continued through mid-February 2019.
- Sampling locations were also located close to significant trucking activity and highways, including within feet of local streets with significant numbers of trucks and cars passing, stopping, and idling. Notably, truck traffic close to commercial area EPA sampling sites in Willowbrook declined significantly following February 15, 2019.
- EPA's and the Village's sampling protocols did not include sufficient chain of custody control, in that they lacked any measures to monitor or prevent pedestrians from approaching, touching, or smoking near the monitoring canisters. In fact, there is evidence of unidentified individuals handling canisters on a day when a "high" reading occurred.

- Samples taken at EPA's Willowbrook warehouse during the sampling period, including in February 2019, were collected near a large diesel generator. While this generator does not operate every day, it did operate on the day that EPA's sampling registered the highest reading at that location. As noted above, diesel engines, particularly if uncontrolled or poorly controlled, emit significant ethylene oxide.

In addition to these particular issues, EPA should acknowledge that the science of measuring very low concentrations of ethylene oxide in air is not well-developed, and laboratories have been pushing the edge of the science in fine-tuning methods to quantify ethylene oxide with low detection limits. This can be seen in the error that EPA's laboratory made on the pre-October 2018 air samples in Willowbrook, in which the laboratory method was not able to distinguish ethylene oxide from trans-2-butene. While that particular error may have been corrected, the state of the science indicates that ambient air monitoring results should be viewed with caution.

Finally, as EPA is aware, Sterigenics has proposed an operating scenario to the State of Illinois, which includes significant engineering changes beyond the facility's already-state-of-the-art emission controls, under which the facility's average hourly emissions of ethylene oxide would be remarkably low. With these improvements, we estimate our annual emissions will be less than 1% of the estimated annual emissions from just the mobile sources in DuPage County, not considering the additional contributions from the myriad other ethylene outside sources. These improvements should be considered in any risk assessment.

We would be happy to discuss these important considerations and answer any questions you may have regarding the information presented in this letter. We would also be willing to provide additional methodological and other details regarding Sterigenics' efforts to identify ethylene oxide background concentrations, ethylene oxide emissions from everyday sources, and data quality issues related to EPA's air monitoring program. Please feel free to contact Kathy Hoffman (630-928-1758; khoffman@sterigenics.com) with any questions that you or your staff may have.

Sincerely,



Philip Macnabb

Attachment